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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,556	07/03/2001	C. Frank Bennett	RTS-0248	2718

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10/07/2003

EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/07/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,556

Applicant(s)

BENNETT ET AL.

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of the region nucleobases 2738 through 2757 in Paper No. 20 is acknowledged. The traversal is on the ground(s) that the newly claimed regions were encompassed in the generic claim 1, drawn broadly to compounds targeting SEQ ID NO:3 as a whole, and therefore were necessarily searched as part of the search for the generic claim. Applicant argues that the search for each of these individual regions would not place an undue burden on the office. This is not found persuasive because The search of the full length of SEQ ID NO:3, which is 2,772 nucleobases in length, is effective to finding art against the broad claim, however, this search is not effective to provide art to determine patentability for each and every individual region within SEQ ID NO:3, including, for example, the 20 base regions instantly claimed. An effective search of each of the regions claimed would require a separate and distinct search for each of these regions, separate and distinct from the search of the full length sequence. The multitude of searches that would be required to find art on each of these individually claimed regions would be an undue burden on the Office, give the heavy burden sequence searching places on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 4-10, and 12-15 are drawn to encompass sequences regions non-elected, these regions are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no

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allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 20.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 20. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (eg. amendments canceling non-elected regions) (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-10 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4-10 and 12-15 are considered to be indefinite because they read on non-elected subject matter, specifically, antisense targeted to non-elected regions within SEQ ID NO:3.

Claim Rejections - 35 USC § 102 or 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 12 and 14 are rejected under 35 U.S.C. 102(a) or 35 USC 103(a) as being anticipated by or obvious over Velculescu et al. (WO 00/77214).

Velculescu et al. (WO 00/77214) disclose 10-mer oligonucleotides that are fully complementary to a region within residues 2738 through 2757 of SEQ ID NO:3 wherein the oligonucleotide is in composition comprising a pharmaceutically acceptable diluent, e.g. water. For example, SEQ ID NO:2472 of Velculescu et al. is fully complementary to residues 2745-2754 of the instant SEQ ID NO:3. The oligonucleotides disclosed by Velculescu et al. are disclosed as tags for use, for example, as a 10-mer probe, however, the oligonucleotides meet all of the structural requirements of the instant claims and would also be expected to specifically hybridize to a nucleic acid encoding HKR1, as per applicant's definition set forth in the specification as filed.

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Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Therefore, the instant invention is anticipated or obvious over Velculescu et al.

Claims 1, 2, 12 and 14 are rejected under 35 U.S.C. 102(b) or 35 USC 103(a) as being anticipated by or obvious over Wang et al. (US Patent No. 5,861,244).

Wang et al. (US Patent No. 5,861,244) discloses an 11-mer oligonucleotide with 9 residues complementary to a region within residues 2738

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through 2757 of SEQ ID NO:3, specifically SEQ ID NO:73 of Wang et al. is complementary to bases 2749-2757 of SEQ ID NO:3, wherein the oligonucleotide is in composition comprising a pharmaceutically acceptable diluent, e.g. water. Wang et al. discloses their oligonucleotide as a probe, however, the oligonucleotide meets all of the structural requirements of the instant claims and would also be expected to specifically hybridize to a nucleic acid encoding HKR1, as per applicant's definition set forth in the specification as filed.

Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Therefore, the instant invention is anticipated or obvious over Wang et al.

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Conclusion

All prior rejections of record, not repeated herein, are considered to be withdrawn in response to Applicant's amendments filed Feb 19, 2003.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
September 26, 2003


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER